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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,522

04/15/2004

Gary K. Michelson

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EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

02/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,522	Applicant(s) MICHELSON, GARY K.	
	Examiner David H. Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Brosnahan, US 5,645,598, and Michelson, US 5,593,409, and further in view of Brantigan, US 4,834,757, or Brantigan, US 5,192,327. Brosnahan discloses providing a first implant (Figure 14) in the form of a threaded partial cylinder having opposite arcuate portions **44** and **46** adapted for placement toward and at least in part within adjacent vertebral bodies (column 2, lines 35-40; column 5, lines 2-6; Figure 1; etc.), providing a second implant **10** or **10A** or **10B**, forming first and second partially overlapping cylindrical holes across the disc space (column 5, lines 46-49 and 55-58), and threading the implants into the holes so as to be nested closely (column 5, line 47; column 2, lines 29-31; column 4, lines 44-46; etc.).

The embodiment of Figures 10-13 includes a hollow interior **40** filled with porous material **42** (column 5, lines 31-45), but Brosnahan lacks openings in the side walls. However,

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openings throughout cylindrical and partial cylindrical surfaces were quite common in the art, as seen, for example, from Michelson '409, the ancestor application of which is referenced by Brosnahan at column 1, lines 37. Although Brosnahan discusses disadvantages of bone grafting (column 1, line 44 et seq.), such a practice is nonetheless widely used, and as seen from both Brosnahan and Michelson '409 (at column 10, lines 8-12 and 35-39, for example), *artificial* materials may alternatively be used. Therefore, the Brosnahan first and second implants being perforated and hollowed in a manner illustrated in the drawings of Michelson '409 would have been an obvious variant in order to enhance fusion throughout the occupied disc space and in order to increase implant stability (Michelson '409: column 4, lines 33-35). Likewise, although Michelson '409 lists various disadvantages of screw threads, such are nevertheless very common, and as seen from the "nested" embodiment of Brosnahan, which is similar to the upper embodiment depicted in Figure 43 of Michelson '409, some of these disadvantages are overcome, and threaded implants do not require impacting with a mallet (Michelson '409: column 10, line 57-60). Thus threaded versions of the Michelson '409 implants **900a** and **900b** would have been obvious (even if such is an obvious step backward relative to the Michelson '409 disclosure taken alone).

Regarding the amended limitation pertaining to a medial side opening "extending along a majority of the length of the implant" (e.g., instant claim 1, lines 14-15), superior-inferior and medial-lateral through openings of such a relative length were well known in the art at the time of the present invention, as seen from the drawings of Brantigan '757 or Brantigan '327. To incorporate one or more of such openings into Brosnahan and Michelson '409 would have been obvious in order to facilitate bone growth "all around and through the implant plug into the bone

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of the vertebrae” (Brantigan ‘757: column 3, lines 54-63; column 3, lines 33-36; column 6, lines 62-65; column 7, lines 20-23; etc.) and/or in order to provide “ample spaces to allow ingrowth of blood capillaries and packing of bone graft” (Brantigan ‘327: abstract, lines 15-17; column 2, lines 52-55; column 4, lines 54-56; column 7, lines 21-23; etc.; Brantigan ‘757: abstract, lines 8-9; column 1, lines 23-26; column 6, line 66, through column 7, line 5; etc.), with further motivation having been provided by both Brosnahan (e.g., figures and abstract) and Michelson ‘409 (column 10, lines 12-16; column 13, lines 9-13; column 14, lines 27-28) similarly teaching elongated slots for such purposes.

Regarding claim 1 and others, the aforementioned “nested” embodiment being installed such that the mid-longitudinal axes converge to one another would have been immediately obvious, if not inherent, from Figure 2 of Brosnahan in order to better conform the trailing ends of the implants to the outer contour of the vertebrae. Regarding claim 3 and others, tapping prior to insertion of the implants would have been obvious to the ordinary practitioner in order to facilitate or ease the action of the screwdriver (Brosnahan: column 4, lines 30-32) and would also have been obvious from column 5, lines 4-5, of Michelson ‘409.

Claims 6, 7, 10-12, 15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boyd et al., US 7,534,265 B1, via provisional application serial no. 60/115,388. Particular attention is directed to Figures 48-51 and page 32, line 18, through page 33, line 15, of said provisional application.

Claims 1-5, 8, 9, 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al., US 7,534,265 B1, via provisional application serial no. 60/115,388. Regarding claim 1 and others, the respective mid-longitudinal axes converging toward one another would

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have been an obvious variant in order to better conform the trailing ends to the outer contour of the vertebrae (page 11, last paragraph, of said provisional application). Regarding claim 3 and others, pre-tapping would have been obvious in order to help ensure proper alignment of the implants (by, for example, avoiding lateral shifting during threaded insertion of the first implant).

Response to Applicant's Remarks

The Applicant apparently asserts that the combination of references applied above and in the previous Office action of September 1, 2009, do not teach or suggest the claimed method, including the newly added step of "introducing osteogenic material through the opening of the medial side" (amended claim 1, line 16). The Applicant's statements overlook the clear teachings (referenced above) in both Brantigan patents of packing bone graft material into the slots. Therefore, no further comment is deemed necessary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**